

REMARKS

Initially, the Applicants note that references to specific claims have been removed from the Specification. The paragraphs containing the objected-to material have been deleted, so removal of the objection in paragraph 2 of the Office Action is earnestly solicited.

Claims 12, 13, 15-21 and 25 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. With respect to claims 21 and 25, the Examiner has asserted that he “is unable to fin[d] support for a rasp being used in the knee area.” Claim 21 has been amended and now recites “plastic material being hard enough for the removal of hip bone.” Such should obviate this rejection.

With respect to claim 20 and the claims dependant thereon (claims 12, 13, 15-19), the Examiner asserts that the “claim(s) contains subject matter which was not described in the specification... Claim 20 appears to imply a limitation directed to the exposing of the plastic material to radiation hardens the material... A limitation directed to the exposure of a plastic material to radiation to harden the plastic material is not supported by the disclosure as originally filed.”

The Applicants respectfully disagree. The Examiner seems to be finding causation in the claim, but it is not so limited – the claim simply recites a physical property condition for the plastic material that must be satisfied after the step of exposing the plastic material to β or γ rays (“exposing said plastic material to β or γ rays, so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone...”). These recitations are clearly supported by the originally filed disclosure, and no new matter has been added to the claims.

The originally filed disclosure teaches rasps, cutting units, and ancillaries made of **plastic that is hard enough to rasp bone**:

However, as **the plastic used is hard enough**, it will be suitable for removing bone and withstanding the pressures associated with the action of a blade on the bone. In addition, by **producing the ancillary in plastic**, there are greater capacities for manufacturing a single-use, so-called “disposable” ancillary.

As a result of an improvement to the invention, **the hardness of the plastic is chosen** close to the bone hardness, for example between 5 and 30% higher.

By producing the rasp or cutting unit in this material therefore, we make sure that the ancillary can only be used for a single operation since the material rapidly wears out during the operation...

Specification page 2, lines 9-19 (Emphasis added).

The originally filed disclosure also teaches that the plastic is exposed to β or γ rays (Specification, page 2, lines 22-29) as part of a sterilization step.

Thus, the originally filed disclosure teaches that the plastic is exposed to β or γ rays, and that after this exposure, a rasp constructed of the plastic is "hard enough...for removing bone." The claims being fully supported by the originally filed disclosure, removal of this rejection is earnestly solicited.

Claims 12, 13 and 20 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has asserted that "[t]he claim language is unclear regarding the hardness of the plastic material, i.e. if the plastic material was hard enough prior to exposure of the radiation and is not changed by the exposure or if the plastic material is hardened by the exposure of the radiation."

It is the belief of the Applicants that the claim is not unclear, and that the physical properties of the plastic *before* exposure to the radiation are not relevant to an understanding of the claim, as the claim only recites a condition for the plastic material that must be satisfied *after* the step of exposing the plastic material to β or γ rays. The issue of indefiniteness depends upon whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). The declaration of Jean François Biegun shows that one skilled in the art would understand what is claimed when the claims are read in light of the specification. See, Declaration filed March 16, 2009. Mr. Biegun's declaration establishes that he made a rasp out of plastic and exposed it to β or γ rays. Mr. Biegun's declaration also establishes that plastic rasps exposed to β or γ rays are "indeed able to rasp bone." Accordingly, there is nothing unclear about the recitation of "exposing said plastic material to β or γ rays, so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone when said rasp is used..." Removal of this rejection is earnestly solicited.

The Applicants do not agree with the Examiner's position that, "[f]or examination purposes, the examiner will treat the limitation as being directed to a plastic material that is hard enough prior to and after exposure of the plastic material to radiation." See, Office Action at paragraph 7. The claim does not require such a reading (again, the recitation only concerns a condition for the plastic material that must be satisfied *after* the step of exposing the plastic material to β or γ rays), but the Examiner's treatment of the claim is inconsistent with what has been disclosed and presented in this case. The originally filed disclosure teaches that exposure to β or γ rays changes the physical properties of the plastic material: "The initial sterilisation [of a plastic rasp] is actually carried out by exposure to γ or β rays. It can only be done once. A second exposure actually degrades the plastic due to the development of free radicals." Specification page 2, line 29 to page 3, line 1. Moreover, Mr. Biegun's declaration establishes that the hardness of a plastic rasp *changes* with exposure to β or γ rays ("It should then be pointed out that with the Beta or Gamma rays exposition pre treatment of the polycarbonate based rasp, it is obtained a value of the hardness which is higher than the one of the bone to be rasped, while without such pretreatment, the hardness stays beyond the hardness of the bone.") Because exposure to radiation changes the hardness properties of the plastic material, the Examiner should not reach the conclusion that a plastic material that is hard enough for removing bone *after* exposure is also hard enough *before* exposure. Thus, the fact that other art references disclose the same types of plastic used in rasps says nothing about whether those plastics are actually hard enough for removing bone.

Claims 15, 16, and 21 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Geisser (U.S. Patent No. 5,454,815). The Applicants respectfully disagree. Geisser does not teach a rasp that is actually hard enough to remove bone. As established in the declaration of Jean François Biegun filed with Amendment E, a rasp constructed according to the concepts of the Geisser invention (without exposure to β or γ rays) has a hardness value *less* than the hardness value of hip or femoral bone. Thus, the rasp of Geisser is not hard enough to remove hip or knee bone. As one having almost 20 years of experience in the art, Mr. Biegun also noted that prior art polycarbonate rasps, such as those

taught in Geisser, have never been able to rasp bone because prior art rasps are not hard enough.

In further support of this contention, the Applicants note that Grunig (U.S. Patent No. 6,120,508), which also lists Mr. Albert Geisser as an inventor, points out that the rasps taught in Geisser had problems when used on hard bone material and with longer application times:

Therefore, disposable rasps have already been proposed for only one-time use. EP-A-0 563,585 and EP-A-0 574,701 show disposable rasps made of plastic. In the production of such rasps from biocompatible plastic material, however, problems may arise with the rasp action, particularly in hard bone material and with longer application times.

Grunig, U.S. Patent No. 6,120,508, Col. 1, lines 30-37. The Examiner will quickly be able to verify that both Geisser and EP0563585 claim priority to the same Swiss patent application, CH19920001043. Thus, the inventors of Grunig appreciated that the prior art rasps "proposed" by Geisser were ineffective. Instead of teaching an improved plastic rasp, those of skill in the art in 1999 reverted to using a rasp having *metal* teeth. Grunig, Col. 2, lines 30-31.

In the Response to Arguments section (see, Office Action at paragraph 14), the Examiner improperly compares the Shore D hardness values of bone with plastic *that has not been exposed to β or γ rays*, and remarks that the claims may not be enabled. However, the Applicants have clearly disclosed that the plastic is hard enough for removing bone, and that the plastic is appropriately hard after exposure to β or γ rays. An instructive comparison of hardness values would be for bone and plastic that *has been* exposed to β or γ rays, and Mr. Biegun's declaration provides this comparison ("It should then be pointed out that with the Beta or Gamma rays exposition pre treatment of the polycarbonate based rasp, it is obtained a value of the hardness which is higher than the one of the bone to be rasped...") Therefore, the enablement concern raised by the Examiner should be withdrawn, and the Examiner should accept the declaration of Mr. Beguin and the arguments presented about the shortcomings of previous plastic rasps (including that the inventors of the Geisser patent went back to using rasps having metal teeth) as being sufficient to overcome the rejection.

The Applicants respectfully assert that Geisser does not teach what is claimed, and therefore, the rejection should be withdrawn. Because the teachings of Geisser are insufficient to support the rejection under § 102(b), and this insufficiency is not overcome by the teachings of Morgan or Judd, the rejections under § 103(a) should also be withdrawn. Thus, all claims are believed to be in condition for allowance.

In view of the foregoing, the Applicants respectfully request the issuance of a Notice of Allowance for claims 12, 13, 15-21, and 25. If any issues remain, a telephone call to the undersigned would be appreciated.

Respectfully submitted,



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